IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** *Cutter v. Ethicon, Inc.* 2:12-cv-01790; *Bates v. Ethicon, Inc.* 2:12-cv-02020; *Daugherty v. Ethicon, Inc.* 2:12-cv-02076; *Morrison v. Ethicon, Inc.* 2:12-cv-02141; and *Miller v. Ethicon, Inc.* 2:12-cv-02187	**MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF MICHAEL KARRAM, MD

Plaintiffs submit this Reply in further support of their Motion to Exclude Expert Testimony of Michael Karram, M.D. (Doc No. 2446).

INTRODUCTION

Defendant proposes to offer into evidence Dr. Karram's opinions regarding the safety and efficacy of the Prolift and TVT-O mesh devices. In their Motion, Plaintiffs demonstrated that Dr. Karram's opinions are not the product of a reliable methodology. Defendant erroneously argues Dr. Karram's unreliable methodology is not relevant to the inquiry regarding the admissibility of his expert testimony. Of course, the reliability of Dr. Karram's methodology is the very essence of the inquiry here.

As shown below and in Plaintiffs' Motion, Dr. Karram should be excluded from offering expert opinions in this case because: (1) he agrees that Prolift should be reserved for high-risk individuals; (2) he admits that strong evidence shows that Prolift is associated with an exposure rate which exceeds what he considers to be acceptable; (3) he employed an unreliable methodology where he selectively discussed favorable findings but completely ignored contrary

findings from the evidence he relied upon; and (4) he offers opinions beyond his expertise and without reviewing the appropriate evidence.

In their Response (Doc No. 2524), Defendant admits many of these errors exist. For example, Defendant **concedes** in its Response that:

(1) Dr. Karram admits that Prolift should be reserved for high-risk patients and not used as a primary treatment for prolapse – undercutting his general opinions that Prolift is safe and effective. Karram Prolift dep. 89:3-6.[1]

(2) Dr. Karram admits that strong evidence shows that Prolift is associated with an unacceptable exposure rate based on his *own* standard for what is acceptable. Karram Prolift dep. 102:13-23.

(3) Dr. Karram failed to address the negative findings and conclusions regarding Prolift in the latest 2016 Cochrane review, which he describes as important Level 1 evidence upon which he relied. Karram Prolift dep. 101:11-18.

Dr. Karram cannot simply ask the Court to accept his proposition that he relied upon the literature and his personal experience. Dr. Karram did not follow a reliable methodology because he failed to explain why he disregarded evidence that he reviewed but contradicts his opinions and failed to explain how he concluded Prolift is generally safe and effective despite concluding that Prolift is only appropriate for high-risk patients. Dr. Karram has not established that he followed a reliable methodology here, and his opinions should be excluded.

ARGUMENT

Dr. Karram has offered general causation opinions purportedly based on his review of the relevant literature and his personal experience. However, "reliance on literature and experience is not dispositive" because the Court must also ensure that the expert has "reliably applied" the methodology with the requisite level of intellectual rigor. *See Carlson v. Boston Scientific Corp.*, 2:13-cv-05475, 2015 WL 1931311, at *14 (S.D. W. Va. April 28, 2015). Dr. Karram did not apply

[1] Michael Karram, M.D. dep. June 28, 2016 (regarding Prolift) (Exhibit 3 to Plaintiffs' Motion to Exclude Expert Testimony of Michael Karram, M.D. (Doc No. 2446-4)) ("Karram Prolift dep.").

a reliable methodology to the facts of the case, because he chose to ignore contrary evidence that he was well aware of.

I. DR. KARRAM'S OPINIONS REGARDING THE SAFETY AND EFFICACY OF PROLIFT ARE THE RESULT OF AN UNRELIABLE METHODOLOGY BECAUSE HE AGREES PROLIFT SHOULD BE RESERVED FOR HIGH-RISK PATIENTS AND HE AGREES THAT POWERFUL EVIDENCE SHOWS PROLIFT IS ASSOCIATED WITH AN *UNACCEPTABLE* EXPOSURE RATE.

Dr. Karram seeks to offer his general opinion that the Prolift device is safe and effective to treat pelvic organ prolapse. Dr. Karram admits he ignored powerful, recent evidence that is contrary to his opinions regarding the safety and efficacy of Prolift. Dr. Karram further admits he has no criticism of the findings, but he simply disagrees with the conclusions. Dr. Karram even agreed during his deposition that Prolift should not be used in primary surgery and should be limited to only high-risk patients – an opinion that contradicts his written opinion.

A. Ethicon Concedes and Dr. Karram Admits that Prolift Should Be Reserved for High-Risk Patients.

In his written report, Dr. Karram opines that "[t]he data, to date, overwhelmingly supports the use of Gynemesh PS and Prolift in the surgical management of POP." Prolift Report[2] at 28. During his deposition, Dr. Karram was shown the 2016 Maher Cochrane review – the most recent high-level evidence examining the safety of the Prolift device. The 2016 Maher Cochrane review concluded that, "[t]he risk-benefit profile means that transvaginal mesh has limited utility in primary surgery [to treat vaginal prolapse]."[3] During his deposition, Dr. Karram agreed with this conclusion. Karram Prolift dep. 89:3-6 ("Q: So you would agree with the author's statement here, that mesh kits such as Prolift should be reserved for high-risk patients? A: I do."). Hence, Dr.

[2] General Expert Report of Michael Karram MD FACOG FPMRS (regarding Prolift), June 3, 2016 (Exhibit 2 to Plaintiffs' Motion to Exclude Expert Testimony of Michael Karram, M.D. (Doc No. 2446-3)) ("Prolift Report").
[3] Maher C, et al., Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database of Systematic Reviews 2016, at 2, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079 (attached as Exhibit 1 to this Reply) ("2016 Cochrane Review").

Karram's deposition testimony – that the most recent high-level data only supported the use of Prolift in high-risk patents – directly contradicts his written opinion that the data "overwhelmingly supports" the use of Prolift for prolapse. This contradiction clearly demonstrates that Dr. Karram could not have followed a reliable methodology to reach his opinion that the data "overwhelmingly supports" the use of Prolift for prolapse.

In its Response, Ethicon completely failed to address this fatal, methodological flaw. Ethicon never addressed Dr. Karram's honest admission that Prolift is only appropriate for high-risk patients. Likewise, Ethicon never explained how Dr. Karram could have followed a reliable methodology to reach his general opinions regarding the safety and efficacy while also believing that Prolift is not appropriate for most patients. By its silence on this issue, Ethicon has effectively conceded that Prolift should only be used with high-risk patients and that Dr. Karram could not have followed a reliable methodology. Accordingly, Dr. Karram's opinions regarding the general safety and efficacy of Prolift should be excluded for failing to establish that they are the product of a reliable methodology.

B. Ethicon Concedes and Dr. Karram Admits that the 2016 Cochrane Review Shows that Prolift is Associated with an *Unacceptable* Exposure Rate, Based on Dr. Karram's *Own* Standard.

Dr. Karram admits that Prolift is associated with an exposure rate that exceeds his own standard for what is acceptable by today's standards. In his Report, Dr. Karram stated, "An overall mesh exposure rate of 3%-8% is an acceptable rate by today's standards." In his deposition, he agreed that an exposure rate of 12% would be above today's standards. Karram Prolift dep. 105:12-15 ("Q: So if, in fact, the exposure rate was 12 percent, that would be above the standard by today's standards? A: I would think so, yes."). Yet, upon review of the most recent 2016 Maher Cochrane Review, Dr. Karram acknowledged that Prolift was associated with a 12% exposure rate. Karram Prolift dep. 102:10-23. In fact, the 2016 Cochrane Review concluded that Prolift is not

appropriate for most patients, in part, based on data showing Prolift was associated with an unacceptably high exposure rate.

In its Response, Ethicon disparages the Cochrane Review as just "one study." However, the 2016 Cochrane Review compiled data from **37 randomized controlled trials** (RCTs) and concluded that the evidence showed Prolift is associated with a 12% exposure rate.[4] Dr. Karam admitted that was the correct finding based on their review of all available evidence. Karram Prolift dep. 102:10-23. Dr. Karram admitted that this exposure rate was unacceptable by his own standard. Karram Prolift dep. 105:12-18. When asked if he had any reason to doubt the findings from the 2016 Cochrane Review, he testified, "I do not." Karram Prolift dep. 103:23-104:1. Rather than offering some critique or reason for disagreeing with the 2016 Cochrane Review, Dr. Karram was forced to cite to other favorable evidence such as the Altman study. However, he admitted that the 2016 Cochrane Review reviewed and included the Altman data. Karram Prolift dep. 142:15-17. Dr. Karram also admitted that the 2016 Cochrane Review is a higher level of evidence compared to his cherry-picked evidence. Karram Prolift dep. 142:22-143:1 ("Q: And, in fact, the 2016 Cochrane Review is a higher level of evidence than the Dr. Landsheere study and the Benbouzoid study, correct? A: Correct.").

In his Report, Dr. Karram opines that Prolift is safe for all women. However, when confronted with the most recent high-level evidence examining the issue, Dr. Karram conceded that Prolift is associated with an *unacceptable* exposure rate according to his *own* standards. Dr. Karram's contradictory positions regarding the use of Prolift demonstrate that his opinions are litigation driven and not the product of a sound methodology.

[4] 2016 Cochrane Review, *supra*, at 1 ("We included 37 RCTs (4023 women)."). However, only 19 of the 37 RCTs provided data on mesh exposure or erosion.

C. Ethicon Concedes and Dr. Karram Admits that the 2016 Cochrane Review is Powerful Level 1 Evidence that Contradicts His Opinions and that Dr. Karram Simply Ignored Its Contrary Findings.

Not only does powerful data exist showing Prolift is unsafe based on his own standards, but Dr. Karram never addressed any of the contrary data. In his Prolift Report, he cites to outdated data from a 2013 Cochrane Review.[5] Then, he selectively cites to favorable findings from the more recent 2016 Maher Cochrane Review, yet he simply ignores the extensive negative findings from the same study. Accordingly, Dr. Karram has not followed a reliable methodology. *See Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 676 (S.D. W. Va. 2014) (holding that an expert's opinion is the result of an unreliable methodology if the expert "fails to account for contrary scientific literature and instead selectively [chooses] his support from the scientific landscape.") (internal citation and quotation omitted); s*ee also Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D. W. Va. Sept. 29, 2014) (excluding expert opinion for failure to explain contrary evidence).

Ethicon concedes that Dr. Karram was aware of the 2016 Maher Cochrane Review when he wrote his Prolift Report. In fact, Ethicon explicitly stated that Dr. Karram "reviewed and evaluated" the 2016 report. Response at 6. As Ethicon correctly states, "[c]hallenges to reasons Dr. Karram *offers* for not relying on certain studies or data points [would] go to the weight of his testimony, not the admissibility of his opinions." Response at 3 (citing *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *8 (S.D. W. Va. May 19, 2016) (emphasis

[5] *See Prolift Report* at 15 ("According to the **latest** Cochrane Review (Maher **2013**) …") (emphasis added); Karram Prolift dep. 94:19-95:3 (Q: If the data on page 15 [of your Report] is, in fact, from the Maher 2013 Cochrane Review, that's actually outdated now, by the new 2016 Maher, isn't that correct? A: That's correct. Q: Okay, And you would like to update that [] to include the actual updated, most recent Cochrane Review that includes all of the current evidence; isn't that correct? A: That's correct.").

added)). However, Dr. Karram has not *offered* any reasons for discounting the findings from the 2016 Maher Cochrane Review.

Instead, Dr. Karram admits he relied upon the paper but simply disagreed with its conclusions. Karram Prolift dep. 101: 11-14 ("Q: And you agree with their findings, you just disagree with their conclusions, correct? A: Correct."). He further admits he never provided any reason in his Report for why he disagreed with the Cochrane findings. Karram Prolift dep. 101:15-18 ("Q: And nowhere in your report do you provide an analysis of why you disagree with their conclusions, other than you cite to some other evidence? A: Correct.").

In an attempt to excuse his unreliable methodology of simply ignoring contrary evidence, Ethicon points out that Dr. Karram cited to some favorable studies. However, the 2016 Maher Cochrane Review looked at those studies and all the other evidence in performing its analysis. Dr. Karram admits as much. Dr. Karram agreed the Cochrane Review appropriately looked at *all* the evidence and performed a correct analysis. Karram Prolift dep. 101:7-10 ("Q: And they looked at all the data and came to these conclusions based off that data, isn't that correct? Q: That's correct.") Dr. Karram testified that he had no criticism or critique of any of the Cochrane analysis in reviewing *all* the medical literature. Karram Prolift dep. 99:16-22 ("Q: Do you have any criticism or critique of their analysis, in reviewing all of this medical literature that reach this conclusion that we just read? A: No.").

Ethicon concedes that the Cochrane Review is "very reputable" and "the highest evidence you can get." Dr. Karram has testified that a Cochrane Review is an "extensive review of the literature on a specific topic." Karram TVTO dep. 110:13-16.[6] Specifically, the 2016 Cochrane

[6] Michael Karram, M.D. dep. June 28, 2016 (regarding TVT-O) (attached as Exhibit 2 to this Reply) ("Karram TVT-O dep.").

Review analyzed and compiled data from **37 RCTs**.[7] Dr. Karram admits that the Cochrane systematic review is considered Level 1 evidence. Karram Prolift dep. 100:20-22. He further characterizes the Cochrane Review as "very reputable," the "highest evidence you can get," and "sound scientific literature." Karram Prolift dep. 100:23-101:3; Karram TVTO dep. 65:14-19. Contrary to Ethicon's argument, the 2016 Cochrane Review is not simply *one* study Dr. Karram overlooked.

In his Prolift Report, Dr. Karram states that the evidence "[o]verwhelmingly [and] consistent[ly] show[s] the success of Prolift at achieving long-lasting anatomic cure with a low rate of complications." *Prolift Report* at 17. However, the Cochrane Review systematically looked at *all* the evidence and performed a meta-analysis. Based on the systematic review of *all* of the available data, the Cochrane Review reached conclusions that are contradictory to Dr. Karram's opinions here. Dr. Karram has offered no explanation for his disagreement with this powerful evidence, other than he simply disagrees with its conclusions. Without some explanation for disagreement with contrary evidence, an expert's methodology is unreliable. *See Eghnayem*, 57 F. Supp. 3d at 676; *see also Sanchez*, 2014 WL 4851989, at *12-13.

II. DR. KARRAM'S OPINIONS REGARDING THE *ADEQUACY* OF ETHICON'S WARNINGS ARE THE RESULT OF AN UNRELIABLE METHODOLOGY AND SHOULD BE EXCLUDED.

Dr. Karram also opines that Ethicon provided "adequate warnings" for its Prolift and TVT-O devices. Again, Dr. Karram has not established that he followed a reliable methodology to reach these opinions. Of course, doctors can opine about the risks that are associated with a medical device and whether those specific risks are included in a certain label. *See Trevino*, 2016 WL 2939521, at *13 (holding that doctor may testify about risks and whether label conveyed those

[7] 2016 Cochrane Review, *supra*, at 1 ("We included 37 RCTs (4023 women).").

risks). However, Dr. Karram's proposed testimony, that Ethicon's warnings were "adequate", involves a legal question and is for the jury to decide. Further, Dr. Karram has not followed any reliable methodology to reach his opinion regarding the "adequacy" of the warnings. Accordingly, this testimony must be excluded. *See id.*, at *45 (holding that "without additional expertise in the specific area of product warnings, a doctor, such as a urogynecologist, is not qualified to opine that a product warning was adequate merely because it included the risks he has observed in his own practice.").

In his Reports, Dr. Karram opines that Ethicon's Prolift IFU and TVT-O IFU "*adequately* describe the risks that are specific or unique to Prolift [and TVT-O]." *Prolift Report* at 21 (emphasis added); TVT-O Report[8] at 4 ("the [TVT-O] Instructions for Use adequately and appropriately warns physicians…"). Dr. Karram's opinion is based on his review of certain federal regulations. *Prolift Report* at 21; *TVT-O Report* at 22. However, in his deposition, Dr. Karram admitted that he had not actually reviewed all of the relevant regulations and was not a regulatory expert. *Prolift Report* at 22; Karram Prolift dep. 59:9-13. In its Response, Ethicon attempts to rewrite Dr. Karram's labeling opinions and argues that they are not based on federal regulations. However, Dr. Karram expressly relied upon these regulations in his Report and his deposition. *Prolift Report* at 21; *TVT-O Report* at 22; Karram Prolift dep. 58:7-11. Additionally, Dr. Karram admits that he did not review Ethicon's internal standards governing the requirements for labeling. Karram Prolift dep. 107:8-10.

Dr. Karram has no objective standard or reliable basis for his opinions that Ethicon provided *adequate* warnings. His testimony is simply based upon his own personal belief which does not reflect a reliable methodology. These and other legal opinions should be excluded. *See*

[8] General Expert Report of Michael Karram MD FACOG FPMRS (regarding TVT and TVT-O), June 3, 2016 (attached as Exhibit 3 to this Reply) ("TVT-O Report").

United States v. McIver, 470 F.3d 550, 562 (4th Cir. 2006) (holding that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013) (excluding testimony regarding legal conclusions such as manufacturer "failed to adequately disclose adverse risks associated with their products" and manufacturer "failed to warn on its label").

III. DR. KARRAM'S OPINIONS REGARDING THE "GENERAL KNOWLEDGE OF ALL DOCTORS" IS THE RESULT OF AN UNRELIABLE METHODOLOGY AND SHOULD BE EXCLUDED.

As noted above, Dr. Karram opines that the Prolift and TVT-O labels "*adequately* describe the risks that are specific or unique to Prolift [and TVT-O]." *Prolift Report* at 21 (emphasis added); *TVT-O Report* at 4. Likely because Ethicon knows Dr. Karram does not have a reliable foundation upon which to offer this opinion, Ethicon studiously avoids mentioning "adequacy" in its argument. Instead, Ethicon argues that Dr. Karram is merely opining about what "all surgeons" know or about the "general knowledge" of all surgeons. However, Dr. Karram has no reliable basis upon which to offer even these opinions. *See Trevino*, 2016 WL 2939521, at *39 (excluding opinion that "surgeons are well aware of clinical implications of complications" when expert has not established opinions are the result of a reliable methodology").

For example, in his Prolift Report, Dr. Karram repeatedly makes statements such as "[T]he actual surgical risks and complications …. are **commonly known** to pelvic floor surgeons." *Prolift Report* at 21-22 (emphasis added). However, Dr. Karram has not demonstrated he followed a reliable methodology to reach these sweeping conclusions. Instead, Dr. Karram admitted that most doctors do not have his same level of knowledge regarding these products – which means his personal knowledge of the complications is not shared by all surgeons.

In its Response, Ethicon conceded and Dr. Karram admitted that he is not commonly

situated because he has a different level of knowledge based on his years working and consulting for Ethicon. Karram Prolift dep. 30:11-21. Ethicon also conceded that not all doctors have time to review all the medical literature regarding these mesh devices and that some doctors are not as knowledgeable as Dr. Karram about the relevant medical literature. Karram Prolift dep. 30:1-10; 112:17-21. Dr. Karram cannot reliably testify, simply based on personal knowledge, as to the "common knowledge of all doctors" – especially if he is differently positioned based on his years with Ethicon. *See Trevino*, 2016 WL 2939521, at *9 (explaining that an expert "may not solely rely on his personal observations when he seeks to provide broad opinions.")

Additionally, Dr. Karram has not established that he followed any reliable methodology to ascertain what is commonly known to all doctors. Dr. Karram admitted that he has no evidence or scientific basis for his assertions regarding the "general knowledge" of surgeons. Karram Prolift dep. 112:8-11. Ethicon conceded that Dr. Karram made no attempt to actually ascertain what is commonly known to other doctors. Karram Prolift dep. 112:14-16.

Instead, the only evidence available on this subject demonstrates that all surgeons do *not* already have all this information. Dr. Karram admitted that many of the organizations that he relied upon, such as ACOG and AUGS, have specifically stated that some doctors needed more information regarding these products. Karram Prolift dep. 72:23-73:20. Dr. Karram offered no explanation for why his opinion differed from the statements of these organizations – statements upon which he relied.

Ethicon has conceded that Dr. Karram did not follow a reliable methodology to reach his opinions about what is "commonly known" by all surgeons. Ethicon further conceded and Dr. Karram has admitted that his personal experience and knowledge is very different than other doctors because he has worked for Ethicon for years. Finally, the position statements from

reputable organizations upon which Dr. Karram relied – the only evidence regarding what is "commonly known" – indicates doctors do not have enough information. As such, Dr. Karram should be precluded from testifying as to what *he* thinks all doctors know.

IV. ETHICON CONCEDES THAT DR. KARRAM WILL NOT TESTIFY ABOUT PATIENT BROCHURES.

In one of the section headers in his Prolift Report, Dr. Karram makes a broad statement about Ethicon's patient brochures. However, during his deposition, Dr. Karram admitted that he did not actually discuss any of the patient brochures in his Prolift Report. In fact, Dr. Karram has not disclosed any opinions regarding the patient brochures as required by Rule 26. Additionally, he admitted that he did not review any regulatory or internal Ethicon standards regarding patient labeling. Instead, he testified that he did not know any even existed. Ethicon conceded these points in its Response. As such, Dr. Karram should be completely precluded from testifying about the patient brochures.

V. DR. KARRAM'S BIOMECHANICAL OPINIONS REGARDING THE PROLIFT MESH ARE BASED ON AN UNRELIABLE METHODOLOGY BECAUSE HE RELIED ON STUDIES REGARDING A *DIFFERENT* MESH CONSTRUCTION AND FAILED TO EXPLAIN CONTRARY EVIDENCE.

As discussed throughout the Motion and this Reply, Dr. Karram has failed to use a reliable methodology in reaching his opinions that Ethicon's Prolift device is safe and effective. Specifically, he ignored evidence, of which he was aware, that contradicted his opinions and instead only discussed favorable evidence. However, should the Court still permit Dr. Karram to testify on these general opinions, the Court should exclude Dr. Karram from offering opinions about the biomechanical safety of the Prolift mesh because he inappropriately relied upon studies regarding a different mesh construction. Additionally, Dr. Karram again failed to address evidence of which he was aware that contradicts his biomechanical opinions even.

A. Dr. Karram Inappropriately Relied Upon Studies Regarding a Completely *Different* Mesh Construction.

Dr. Karram admits and Defendant concedes that he did not discuss *any* evidence in his Report addressing the biomechanical safety of the *Prolift* device. Instead, Dr. Karram discussed evidence regarding the mesh used in mid-urethral slings to treat incontinence. *Prolift Report* at 12, 24. However, Dr. Karram admitted that the mesh used in the mid-urethral slings is a completely different mesh construction than the Gynemesh PS (Prolene Soft) mesh used in Prolift, which results in a different pore size and weight. Karram Prolift dep. 49:14-50:12. Dr. Karram admitted that he is not a biomechanical engineer and that he does not know the clinical impact of the biomechanical differences between the different meshes.[9] Karram Prolift dep. 53:9-54:2. Further, he testified that he was not aware of any evidence supporting his proposition that the evidence regarding the mid-urethral slings is relevant to assessing the safety of the Prolift mesh. Karram Prolift dep. 51:20-24.

B. Ethicon Concedes that Dr. Karram's Opinion that the Foreign Body Reaction Terminates After Six to Eight Weeks Has No Scientific Support and Was Not Properly Disclosed Pursuant to Rule 26.

In his deposition, Dr. Karram opined that the Prolift mesh elicits a foreign body reaction once implanted that ends around six to eight weeks. Karram Prolift dep. 107:11-20. Dr. Karram did not disclose this opinion in his Prolift Report and could not cite to any evidence supporting his proposition. In its Response, Defendant acknowledged that Dr. Karram was unable to point to any evidence supporting this opinion and also that "this very specific opinion [was] not addressed in

[9] Without any scientific support or explanation, Defendant incorrectly argues that all mesh products using "Prolene" have the same biomechanical properties. Response at 10 ("While Dr. Karram does rely on and cite to studies specifically looking at mid-urethral sling devices, he does so in regard to the properties of Prolene mesh – mesh which is used both in these slings and the Prolift device.") First, the Prolift device is not constructed of "Prolene" mesh. While the TVT mid-urethral sling is indeed made of Prolene mesh, the Prolift device is made from Gynemesh PS (Prolene-Soft), which is a different, newer mesh construction. Second, the specific mesh construction determines the pore size and weight of the mesh, which in turn affects the level of inflammation and foreign body reaction. Biomechanical experts for Plaintiffs and Defendants appropriately address these issues.

his report." Response at 11. This opinion should be excluded because it is not the result of a reliable methodology and was not disclosed in Dr. Karram's Rule 26 report.

C. Dr. Karram Cites No Evidence for His Opinions Regarding Degradation and Instead Ignores Evidence that Contradicts His Opinions and that He Included on His Reliance List.

Defendant next argues that Dr. Karram's opinions regarding the biomechanical aspects of the mesh were based on his review of the general medical literature, where he found no literature "concluding that Prolene degraded in any clinically meaningful way." *Prolift Report* at 10. However, he could have simply looked on his reliance list for such evidence. Dr. Karram included literature on his reliance list, that he purportedly reviewed, which concluded that the plastic (polypropylene) used in these meshes degraded. Karram Prolift dep. 63:19-22 ("Q: Based on the evidence in this article, would you agree that there is evidence of degradation in polypropylene implants? A: This article suggests that, yes."). Again, Dr. Karram could not provide any scientific basis for discounting this contrary evidence. Karram Prolift dep. 64:22-65:4.

Defendant then falls back on sweeping assertions that Dr. Karram's biomechanical opinions are based on his review of medical literature and reliance on education, training, and experience. *Prolift Report* at 11. Defendant cites to no deposition testimony or sections in Dr. Karram's reports where he describes any reliable methodology for reaching these biomechanical opinions, that exceed his expertise. Indeed, Dr. Karram has not actually cited to any evidence supporting his biomechanical opinions regarding the *Prolift* mesh and has not followed a reliable methodology in reaching his other biomechanical opinions. As such, this testimony should be excluded.

CONCLUSION

Dr. Karram has not established that he followed a reliable methodology in reaching his opinions regarding the safety and efficacy of the Prolift device, the adequacy of Ethicon's

warnings, the adequacy of Ethicon's patient brochures, the "common knowledge" of all doctors, or the biomechanical aspects of the Prolift mesh. In fact, Dr. Karram even admits that the Prolift device should only be used in limited circumstances with high-risk patients. For these reasons, the Court should grant Plaintiffs' Motion and exclude the general causation expert testimony of Dr. Michael Karram.

Respectfully submitted this 18th day of August, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF MICHAEL KARRAM, M.D.,** on August 18, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

s/ Jenelle Cox